Storage and Handling

The success of your efforts to prevent vaccine preventable diseases is dependent in part on proper storage and handling of vaccines. Exposure of vaccines to temperatures outside the recommended ranges can cost your practice thousands of dollars in wasted vaccine and revaccination. Errors in storing and handling your vaccines can also result in the loss of patient confidence in your practice when repeat doses are required. Vaccines are fragile and must be kept at the recommended temperatures at all times. It is better to *not vaccinate* than to administer a dose of vaccine that has been mishandled.

Live vaccines, like varicella and LAIV, can tolerate freezing and *must* be stored in the freezer. MMR vaccine is usually stored in the refrigerator, but it can also tolerate freezing temperatures. Live virus **vaccines deteriorate rapidly after removal from the freezer,** or from the refrigerator in the case of MMR. On the other hand, **inactivated vaccines are damaged by exposure to freezing temperatures.** Inactivate vaccines exposed to freezing temperatures should not be used. However, they can **tolerate short periods of time out of refrigeration**, although potency can be adversely affected if left out too long.

Vaccines must be stored properly from the time they are manufactured until they are administered to your patients. This is referred to as the cold chain. All healthcare providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed. Each office should **develop and maintain a detailed written storage and handling protocol**; **assign storage and handling responsibilities to one person**; **designate a backup person**, and **ensure that both of them are provided with training on vaccine storage and handling**.

Vaccine storage units must be selected carefully and used properly. Refrigerators without freezers, and stand-alone freezers, are usually better at maintaining the required temperatures. However, a combination refrigerator-freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate door.

Any refrigerator or freezer used for vaccine storage must be able to **maintain the required temperature range throughout the year**. It must be **large enough to hold the year's largest vaccine inventory**, and must be **dedicated to the storage of biologics**. Food and beverages should *not* be stored in vaccine storage units. **Small dorm style refrigerators** with a single exterior door may only be used to store small quantities of inactivated vaccines or MMR. They should never be used to store varicella vaccine or LAIV, because the freezer compartment cannot maintain the required temperature without freezing everything else in the unit.

Most vaccines require storage temperatures of **35° to 46°F**, which is **2° to 8°C**, with a desired **average temperature of 40°F,** or 5°C. Both varicella vaccine and LAIV must be stored in a continuously frozen state at **5°F**, which is **-15°C**, or colder. If you are using both the refrigerator and freezer to store vaccines, be careful not to make the freezer so cold that the refrigerator temperature drops below the recommended temperature range.

Proper temperature monitoring is key to proper cold chain management. You should have a supply of temperature monitoring records like this. The record has a space for recording both refrigerator and freezer temperatures. It has a cross-hatched or colored area that gives you a visual cue when the temperature is out of range. **Check and record the temperatures twice a day** - once in the morning and once before you leave at the end of the workday. It is important to **keep temperature logs for at least 3 years**, unless state statutes or rules require a longer period. As the refrigerator or freezer ages, you can track recurring problems or identify how long problems have existed. Equally important to checking the temperatures is **to take immediate action when the temperature is outside the recommended range**. Remember, any mishandled vaccines should *not* be administered. It is especially important that inactivated vaccine that has been exposed to freezing temperature *not* be administered.

Both the refrigerator and freezer compartments should have their own certified calibrated thermometer. Here are some examples of thermometers that can be used, including **biosafe liquid**, **continuous graphic**, and **minimum maximum**. If you are using a continuous recording thermometer, even though it is recording the temperatures for you, it should still be checked twice each day to make sure the temperatures are in range.

To keep the refrigerator and freezer cold, the unit must be in good working condition, and it must have power at all times. There are several things you can do to prevent problems. Your refrigerator should have a **plug guard or a safety lock plug** so that it cannot be pulled out accidentally. **Post a warning sign at the plug and on the refrigerator**. **Label the circuit breakers** to alert janitors and electricians not to unplug the vaccine storage unit or turn the power off. And finally, you may want to **install a temperature alarm** to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained. You can help stabilize the temperature in the **refrigerator** by keeping containers of water inside. We suggest you remove the vegetable bins and put your water bottles in their place. Keep extra cold packs or blue ice in the **freezer**. This added bulk helps keep temperatures stable with frequent opening and closing of the doors, and in the event of a power failure.

Providers should also never store vaccines in the door of the freezer or the refrigerator, or in the vegetable bin. The temperatures in these areas are not stable. Use these areas to store liquid bulk and cold packs. You can store diluent that is packed separately from its vaccine in the refrigerator door, but be sure it is clearly marked.

We are frequently asked about prefilling, or drawing up doses of vaccine before they are actually needed. Questions about this are particularly common during influenza vaccination season. The National Immunization Program strongly discourages filling syringes in advance, for a number of reasons. The most important reason to avoid this practice is that filling a syringe before it is needed **increases the risk for administration errors**. Once in the syringe, it is difficult to tell which vaccine is which. Prefilling syringes **increases the chance of vaccine wastage** and increases the risk of **inappropriate vaccine storage conditions**. Prefilling syringes **may result in bacterial growth in the vaccines** that do not contain a preservative, such as vaccines supplied in single dose vials. There are no stability data for vaccine stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby **reduce vaccine potency**. As an alternative to prefilling syringes, you may want to consider using manufacturer-supplied prefilled syringes for large immunization events, such as community influenza clinics. Syringes other than those filled by the manufacturer are designed for immediate administration and NOT for vaccine storage. Vaccine manufacturers do not recommend predrawing influenza vaccine for a large influenza clinic. NIP also strongly discourages this practice.

If a limited amount of vaccine must be predrawn for a mass immunization clinic, then follow these guidelines: **Administer only one type of vaccine** at the clinic. If more than one vaccine is to be administered, **separate vaccine administration stations by vaccine type** to prevent errors. **Transport the vaccine to the clinic in the manufacturer-supplied packaging at the recommended temperature.** If the vaccine is stored in a transport container, **use an insulated barrier such as bubble wrap or brown packing paper between the vaccine and the cold or frozen packs**. **A single layer of towel over ice is *not* adequate protection**. Upon arrival at the clinic, each person who will be administering vaccine may **draw up a small quantity of vaccine to meet the initial needs of the clinic – no more than 1 vial or 10 doses**, whichever is more. The vaccine administrators can **replenish their vaccine supply and prefilled syringes throughout the day. Monitor patient flow** to avoid drawing up unnecessary doses. **Discard any syringes other than those filled by the manufacturer at the end of the clinic day.** Predrawn vaccine should not be used on subsequent days. Let me repeat that: we recommend you discard any syringes *you* prefilled at the end of the clinic day. Predrawn vaccine should *not* be used on subsequent days.

Vaccine inventory control is a critical part of vaccine quality management. Providers need to know how much vaccine they have on hand, when it arrived, and when it expires. As part of inventory control, providers should **conduct a monthly vaccine inventory** to be sure they have enough to meet their needs. However, **avoid stocking excessive vaccine supplies**, as this leads to vaccine wastage when vaccines become outdated. Also **include diluents in the stock control procedures** and ensure adequate diluent supplies are available. Vaccines may only be reconstituted with the specified diluent. Diluents are not interchangeable. Providers should **monitor the expiration date** of their vaccine

and diluent supplies and **rotate stock to avoid waste from expiration**. **Expired vaccine and diluent should never be used**. Finally, to help protect your vaccine supply, **limit access to authorized personnel only**.

It is critical that every clinic have a written emergency vaccine retrieval and storage plan. The most important part of this plan is to identify a location with a backup generator where a provider can move their vaccine in the event of an emergency, such as an equipment failure or power outage. Consider contacting a local hospital, the Red Cross, or a long term care facility as a backup site. Information to assist in developing a written plan is available on the National Immunization Program website. In fact, there are a number of useful storage and handling resources in Appendix D of the Pink Book. We will provide several other helpful items on the broadcast resource website.

The National Immunization Program also has a new smallpox vaccine storage and handling training program. The program consists of four web-based self-study modules that participants can complete at their own pace. The program offers continuing education credit, and is free of charge. You can locate it through our broadcast resources web page.

Other tools will also be available soon from CDC. A vaccine storage and handling CD-ROM and a web based storage and handling training module for vaccine providers are both expected to be available in the Fall of 2004. We will announce their availability on the NIP website.

In order for patients to be protected by vaccines, vaccines must be stored and handled with care. With a few simple steps and good practices to maintain proper vaccine storage and handling, we can ensure that the full benefit of immunization is realized.